

## Remarks

By the above amendment and remarks, applicant has amended the several claims in order to define the invention patentable over the new prior art.

### **The rejection under §101**

Claims 18-20 and 22 are currently amended in order to overcome the rejection in the O.A.

### **The rejection under §112**

Claim 15-21, 23-24, and 26 are currently amended in order to overcome the rejection in the O.A.

Claim 27 was amended.

### **The rejection under §102**

Fogarty et al. (6,110,198) discloses a three module tubular prosthesis that is inserted to within the aneurism area mostly in separated modules (shown in Figure 5A and B). It should be noted that the modules of the present invention cannot be inserted as separated modules in any case. As disclosed in col. 9 lines 57-58 the edges of the prosthesis are tapered in opposed to the graft of the present invention that is of substantially constant cross section and can be cut prior to surgery in any place according to the physical properties of the aneurism

in the specific patient to be treated. Claim 1 is amended accordingly. Moreover, the modules are "resilient radially expandable tubular frame", while the docking head of the present invention is a firm body.

In regard to the cuffs (docking heads); Fogarty et al. discloses in Figure 3A and explains in Col. 9 line 66 to Col. 10 line 25, a cuff having "three distinct axial regions" having a proximal sealing region to be pressed against the body lumen, a body region with expanding frames that anchor the prosthesis and third region that is smaller in diameter and has an inelastic liner. This is in oppose to the docking heads of the present invention that are not built from distinct areas and are hollow cones that are made of the same material and properties along the docking head length and are elastic (elasticity is specifically claimed in claim 17).

The docking head of the present invention are movable along the graft and can be adjusted to the graft prior to insertion into the vessel and not inserted as separated modules during surgery as Fogarty et al disclose.

The barbs of Fogarty et al. are provided in the portion 84 of the cuff, a portion that is inserted and connected to within the prosthesis and are aimed at better connecting the cuff to the prosthesis "the interface end optionally includes barbs which lock the relative position of the prosthesis modules at the coupling" (col. 10 lines 26-28). Moreover, "the barbs are generally axially oriented in one or both axial directions" (col. 10 lines 30-31) since they are axially pushed against the

prosthesis due to expansion and are provided on a surface that consist several components. In the docking head of the present invention, the barbs are aimed at connecting the graft to the vessel and therefore are not directed and can not be directed in both sides and are claimed to be outwardly pointing and inclined in Claim 11 and specifically claimed to be in the direction of the graft in Claim 21 so as to nail to the vessel when pulled backwardly rather than axially through expansion. There is almost no axial expansion of the claimed docking heads.

### **The rejection under §103**

As mentioned previously regarding the "docking head" of Baker et al. (6,729,356), it comprises a sealing member 40+44 (Figure 1) out of two members from which the "docking head" consist of. This member 40 is solely aimed at sealing the coupling between the vessel and the graft through the biasing member 44 that "serves to urge the sealing member 40 from a first pressed position to a second expanded position.... The biasing member 44 provides a continuous and outwardly directed urging force pressing the sealing member against the diseased vascular wall...." (col. 5, lines 29-38). The movement of the sealing member is solely radially and in the present invention, each docking head is moved to different direction.

The vascular device of the claimed invention comprises docking heads that is acting as sealing member not through pressure and are designed for guiding,

anchoring and sealing in one member that is not composed of layers, members, or wires. As previously explained, the attachment of the docking head in the claimed invention is by nailing the docking head to the corresponding vessel using the barbs and not by expansion as described by Baker et al. Moreover, the hooks of Baker et al. are provided in the attachment means and not in the sealing member 44 and merely enhance the attachment between the attachment system and the vessel and doesn't form the connection and sealing as in the claimed invention.

Barbs that are incorporated in systems such as Baker et al. and others are not oriented in a certain direction since the system is expandable or extendable and the barbs are pushed axially towards the vessel walls. The direction of the barbs is in many cases random when the wires to which the barbs are connected are expanding. The barbs are generally for additional fixation of the system to the vessel or the attachment system to the graft as in Fogarty et al. Therefore, it is not obvious to use directed barbs as claimed in the claimed invention. The claimed barbs are nailed to the vessel when the graft is outwardly pulled, an action that is not performed in neither of the prior art documents and therefore, not obvious. Initially the barbs are adjacent to the docking head and when nailed, are moving away towards the vessel.

As mentioned previously, Randall (US 2003/0158595) discloses a bifurcated graft provided with ring stents 10, 16 and 18 adapted to be in enlarged or deployed

states as explained in Paragraph 0017. Moreover, Randall's ring stents are slender threads (Figures 1 and 2) that are made of a shape memory material. Fogarty et al. disclose outward flare cuff modules that are also pressed against the body lumen. Both characteristics are in oppose to the general structure and operation of the claimed invention, in which the docking head is made as thin walled truncated cone that is substantially not expandable as both Randall's and Fogarty and is not intended to be pressed towards the walls of the vessel. Therefore, Randall even in view of Fogarty can not predict the use of a docking head having characteristics that oppose the characteristics of both of them.

Elliot (US 2003/0346567) discloses a skirt that is an extension of a tubular body. In the claimed invention, the docking head (parallel to Elliot's skirt) is a separated module that is connected to the graft and not an extension. The skirt is expandable as in other prior art so as to push towards the vessel. Wall engaging members 195 of Baker et al. (US2002/0091439) are provided by welding on legs 181, 182 rather than on the body of attachment system 175 and 176. A combination between the skirt and the engaging members is not likely to be predicted. Moreover, the functionality of Baker's engaging members is totally different than the functionality of the claimed barbs; therefore, is not obvious also to a skilled person in the art.

### Conclusion

For all of the above reasons, the applicant submits the Claims in proper form and the Claims are now defined patentable over the prior art. Therefore, the application and all claims are now in a condition for allowance. A prompt notice of allowance is respectfully requested.



N. Paul Friederichs, Reg No 36, 515  
PO Box 48755

Coon Rapids, MN 55448

Tel: 763-862-8987

763-862-2437

Fax: 763-862-0518

## **Claims as currently presented**

Claims 1-10 have been previously cancelled.

11. (Currently amended) A vascular device for treating a vessel with aneurysm comprising:
- a tubular graft having a proximal portion and a distal portion and having substantially constant cross section along the graft;
  - at least two substantially non-extendable docking heads comprising thin-walled truncated cones wherein a first docking head is provided at said proximal portion and at least one second docking head is provided at said distal portion and wherein at least one of said at least two docking heads is movable in respect to said graft and is adapted to be adjusted and fastened to a suitable positioning on said graft before insertion of the vascular device to the vessel;
  - a plurality of outwardly pointing and inclined barbs is connected to at least one of said at least two docking heads;
- wherein the vascular device is capable of being coupled to the vessel on both healthy sides of the aneurysm by said at least two docking heads that act as guiding, anchoring and sealing means in a suture-less and rapid manner.

12. (Previously cancelled)

13. (original) The vascular device as claimed in Claim 11, wherein said graft is a bifurcated graft.
14. (previously cancelled)
15. (currently amended) The vascular device as claimed in Claim 11, wherein said at least one of said at least two docking heads is coupled to said suitable positioning by a coupler selected from a group consisting of fit, glue, sutures, clips, and staples.
16. (currently amended) The vascular device as claimed in Claim 11, wherein said at least two docking heads have an outer diameter so as to couple the graft to the vessel, and wherein said thin-walled truncated cone has a passage that corresponds to an outer diameter of said graft.
17. (currently amended) The vascular device as claimed in Claim 16, wherein said thin-walled truncated cone is elastic.
18. (currently amended) The vascular device as claimed in Claim 16, wherein said thin-walled truncated cone has a concaved, convex or straight profile sized to correspond to the vessel profile.



19. (currently amended) The vascular device as claimed in Claim 16, wherein an outer diameter of said thin-walled truncated cone is sized to be substantially smaller diameter than an internal diameter of the vessel so as to guide it into the vessel.
20. (currently amended) The vascular device as claimed in Claim 16, wherein an outer diameter of said thin walled truncated cone is of substantially smaller diameter than the vessel is sized to so as to assure firm sealing of the vessel.
21. (original) The vascular device as claimed in Claim 16, wherein said barbs are flexible and are inclined towards a direction of said graft.
22. (currently amended) The vascular device as claimed in Claim 11, wherein some of said plurality of barbs have a length the thickness of a vessel's wall so as to enable perforating the vessel's wall.
23. (currently amended) The vascular device as claimed in Claim 11, wherein some of said plurality of barbs are bent so as to establish a concave profile in respect to a radial cross section of said thin-walled truncated cone.

24. (currently amended) The vascular device as claimed in Claim 11, wherein some of said plurality of barbs are bent so as to establish a convex profile in respect to a radial cross section of said thin-walled truncated cone.
25. (Previously cancelled)
26. (currently amended) The vascular device as claimed in Claim 16, wherein said thin-walled truncated cone is provided with a plurality of open slits adapted to allow said truncated cone to curtail its larger diameter.
27. (currently amended) The vascular device as claimed in Claim 11, wherein said thin-walled truncated cone is outwardly everted over a guiding end of said graft.
28. (Previously amended) The vascular device as claimed in Claim 11, wherein said at least two docking heads as well as said graft are made as separate modules that can be selected according to individual vessel anatomy prior to the insertion of the vascular device into the vessel.